



CFSAN/Office of Cosmetics and Colors
April 19, 2001; Updated March 31, 2005

Phthalates and Cosmetic Products

The Centers For Disease Control (CDC) released a report on March 21, 2001, entitled "National Report on Human Exposure to Environmental Chemicals." The report described a survey of a small segment of the U.S. population for environmental chemicals in urine. One group of chemicals the survey identified was phthalates.

The following is intended to answer questions on the subject of phthalates in cosmetics.

What are phthalates?

Phthalates are a group of chemicals used in hundreds of products, such as toys, vinyl flooring and wall covering, detergents, lubricating oils, food packaging, pharmaceuticals, blood bags and tubing, and personal care products, such as nail polish, hair sprays, soaps, and shampoos.

What phthalates are used in cosmetics?

The principal phthalates used in cosmetic products are dibutylphthalate (DBP), dimethylphthalate (DMP), and diethylphthalate (DEP). They are used primarily at concentrations of less than 10% as plasticizers in products such as nail polishes (to reduce cracking by making them less brittle) and hair sprays (to help avoid stiffness by allowing them to form a flexible film on the hair) and as solvents and perfume fixatives in various other products.

Do phthalates affect human health?

It's not clear what effect, if any, phthalates have on health. An expert panel convened from 1998 to 2000 by the National Toxicology Program (NTP), part of the National Institutes of Health, concluded that reproductive risks from exposure to phthalate esters were minimal to negligible in most cases.

In 2002, the Cosmetic Ingredient Review (CIR) reaffirmed its original conclusion (reached in 1985) that DBP, DMP, and DEP are safe as used in cosmetic products. The panel concluded that exposures to phthalates from cosmetics are low compared to levels that would cause adverse effects in animals. (The CIR is an industry-sponsored organization that reviews cosmetic ingredient safety and publishes its results in open, peer-reviewed literature.)

FDA reviewed safety and toxicity data (including the CDC data) for phthalates in 2001 and 2002 as well as CIR conclusions that were based on reviews of the data in 1985 and 2003. FDA noted that the CDC survey report in 2001 was not intended to make an association between the presence of environmental chemicals in human urine and disease, but rather to learn more about the extent of human exposure to industrial chemicals. While the CDC report noted elevated levels of phthalates excreted by women of child-bearing age, neither it nor the other data reviewed by FDA established an association between the use of phthalates in cosmetic products and a health risk. As a result, FDA determined that there was insufficient evidence upon which to take regulatory action.

How do I know if there are phthalates in the cosmetics I use?

Under the authority of the Fair Packaging and Labeling Act (FPLA), FDA requires an ingredient declaration on the cosmetic products sold at the retail level to consumers. Consumers can tell whether some products contain phthalates by reading the ingredient declaration on the labels of such products.

However, the regulations do not require the listing of the individual fragrance ingredients; therefore, the consumer will not be able to determine from the ingredient declaration if phthalates are present in a fragrance. Also, because the FPLA does not apply to products used exclusively by professionals—for example, in salons—the requirement for an ingredient declaration does not apply to these products.

What is FDA's role?

FDA continues to monitor consumers' potential exposure to phthalates from the use of cosmetic products. FDA's Center for Food Safety and Applied Nutrition (CFSAN) included the following two projects among its [program priority items for 2004](#): (1) Develop an analytical method for the determination of phthalates in cosmetic products, and (2) conduct a survey of products to determine the contribution of phthalates to human exposure. FDA has completed both of these projects. Next steps include an exposure estimate and plans for a risk assessment as additional support in determining whether any further action is necessary.

At the present time, FDA does not have compelling evidence that phthalates, as used in cosmetics, pose a safety risk. If FDA determines that a health hazard exists, the agency will advise the industry and the public, and will consider its legal options under the authority of the Federal Food, Drug and Cosmetic Act in protecting the health and welfare of consumers.

For related information, see [FDA Authority Over Cosmetics](#).